As Congress drew its summer session to a close in late July, three bills were introduced on the House and Senate floors calling for significant changes to the 340B program including measures that would extend the 340B program to include inpatient drugs, expand the program to include new entities, address program oversight and transparency, and allow covered entities to partner with multiple contract pharmacies.

The bills—H.R. 3547, S. 1563, and S. 4—were all introduced within the last two days of the summer session, and were referred to their appropriate committees before the session was closed.

Introduced by a bipartisan group of lawmakers led by Rep. Jo Ann Emerson (R-MO) and Rep. Bobby Rush (D-IL), H.R. 3547 calls for an extension of the 340B program to include inpatient drugs purchased by participating hospitals and proposes that small rural institutions known as “critical access hospitals” be included as covered entities under the program.

Entitled the “Safety Net Inpatient Drug Affordability Act,” the bill is the first piece of legislation introduced in Congress this year that would require manufacturers that participate in Medicaid to offer 340B inpatient discounts to disproportionate share hospitals (DSH) in the program.

Key 340B Measures Introduced in Congress

**H.R. 3547 - “Safety Net Inpatient Drug Affordability Act”**

Would extend 340B discounts to inpatient drugs and expand the program to include critical access hospitals

**S. 1563 (Sec. 302) - “ABCs of Children’s Health Care Act”**

Calls for the expansion of the program to include children’s hospitals

**S. 4 (Sec. 332) - “Healthy America Act of 2005”**

Addresses program oversight and multiple contract pharmacy arrangements

The bills—H.R. 3547, S. 1563, and S. 4—were all introduced within the last two days of the summer session, and were referred to their appropriate committees before the session was closed.

Currently, the 340B program only guarantees discounted pricing on the outpatient side, though manufacturers are permitted to offer discounted inpatient pricing to 340B hospitals on a voluntary basis without impacting the prices they are obligated to provide to disproportionate share hospitals (DSH) in the program.
HRSA and CMS Nearing an Agreement on 340B Ceiling Price Calculations

After close to a year during which the Office of Pharmacy Affairs (OPA) was not able to accurately verify 340B pricing, the Health Resources and Services Administration (HRSA) is close to reaching an agreement with the Centers for Medicare and Medicaid Services (CMS) that will once again make it possible for OPA to verify ceiling prices. In addition, the interagency agreement would make OPA responsible for calculating the prices for the first time.

The new agreement, which is “in its final throes” according to OPA Director Jim Mitchell, is currently being reviewed by the two agencies. Once the contract has been completed and approved, it will be signed by both HRSA and CMS and applied to fiscal year 2006, which begins on October 1 and ends on September 30 of next year.

Mitchell says that the contract will allow his office to begin calculating 340B ceiling prices as soon as the agreement goes into effect.

Under past agreements, CMS was responsible for calculating ceiling prices and providing them to OPA. However, since an agreement was never reached for fiscal year 2005—beginning on October 1, 2004—OPA has not had access to this information since that time.

As a result, Mitchell’s agency has been unable to verify pricing for covered entities that are concerned about potential overcharges by manufacturers in the program.

“We have not done any of that this year,” Mitchell says. “This agreement will allow us to respond to groups representing [340B entities] that want to know if the prices they are receiving are above or below the ceiling price. It will give us the tools to start validating pricing again.”

The development of the agreement was discussed at the 340B Coalition Conference in Washington, DC on July 11 by both Mitchell and CMS Medicaid Policy Analyst Marge Watchorn during a session on enforcement of the 340B statute.

Citing efforts by the US Department of Health and Human Services Office of Inspector General (OIG) to verify 340B pricing, Watchorn wondered aloud whether it was appropriate for CMS “to be calculating a ceiling price on behalf of another agency,” adding that OPA staff was better suited to calculate the ceiling prices because they are responsible for administering the program.

The data that will be provided to OPA under the agreement are the Average Manufacturer Price (AMP) and the Medicaid unit rebate amount for 340B covered outpatient drugs.

In order to perform the calculations, OPA will also contract with a third party to provide package size data. The identity of the third party contractor has not yet been disclosed.

“From that information, using the [340B pricing] formula, we will begin computing ceiling prices and we will validate that information through various mechanisms,” says Mitchell.

Under the agreement, OPA staff will be responsible for maintaining the pricing files and following up with industry to investigate potential overcharges. The system that the agency will use for calculating these prices is currently being designed by a systems development contractor.

The need for such an agreement was highlighted last year when OIG withdrew its June 2004 report on the appropriateness of 340B pricing (The Monitor, November 2004). According to a letter written by HHS Inspector General Daniel Levinson, one of the reasons for the withdrawal was that CMS had provided OIG with data from the inappropriate time period, thus compromising the results of their analysis.

The June report also highlighted the deficiencies in the administration of the program. For instance, the report stated that OPA lacks sufficient data against which to verify manufacturers’ calculations of 340B ceiling prices.

The Health Resources and Services Administration (HRSA) has been given a green light by the US Department of Health and Human Services (HHS) to publish new guidance on key issues in the 340B program including the program’s definition of “patient” and the use of multiple contract pharmacies, according to Office of Pharmacy Affairs (OPA) Director Jim Mitchell.

The guidance, which are now being drafted, will first be published in a Federal Register notice and made available for public comment. It will then be evaluated once again by HHS before it is submitted as final regulations.

While he is unable to speculate about when the notices will be released, Mitchell insists that they are among the “highest priorities in my office” and that providing more concrete guidance on the patient definition is of particular importance to HHS.

The question of how to define a covered entity patient received a great deal of attention at the 340B Coalition Conference in Washington, DC from July 11-13. The 340B patient definition is significant because 340B entities are only permitted to distribute drugs purchased through the program to individuals who are “patients” of their entity.

According to a Federal Register notice released on October 24, 1996, an individual is a patient of a 340B entity only if: (a) the entity has a relationship with the patient such that the entity maintains records of the individual’s health care, (b) the individual receives care from either an employee of the entity or someone who “provides health care under contractual or other arrangements,” such that the responsibility for care remains with the covered entity, and (c) the individual receives care that is consistent with the range of services for which the entity receives federal grants. (The third test does not apply to disproportionate share hospitals.)

“An individual will not be considered a patient...if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs,” the notice states.

Mitchell says that this definition has “served us well over the years,” though he acknowledges that there are a number of ambiguities in the definition that should be addressed with more detailed guidance from HHS. Specifically, HRSA hopes to tighten the definition to “remove any grey areas” and ensure that entities have a clear idea of what is permitted under the law.

“The [340B] model is being pushed in a number of areas,” says Mitchell. “There are questions out there about whether some models exceed the intent of the definition. We want to help entities make better decisions about who constitutes a patient and under what circumstances.”

“There are questions out there about whether some models exceed the intent of the [patient] definition. We want to help entities make better decisions about who constitutes a patient and under what circumstances.”

Jim Mitchell
Office of Pharmacy Affairs

The ambiguities in the patient definition have led some covered entity groups to operate based on their interpretations of the guidelines. For instance, the Public Hospital Pharmacy Coalition (PHPC)—an organization that represents approximately 300 hospitals that participate in the program—recently released a set of principles that the Coalition uses to guide its members on how to apply the patient definition and prevent diversion to non-patients.

On August 3, PHPC sent a letter to HRSA Administrator Elizabeth Duke to make the agency aware of its principles and to request that the patient definition be clarified.

Among other things, the letter states that the 340B guidelines are unclear on how to determine when a prescription written by a non-hospital physician may be filled under the 340B program.

To correct this ambiguity, PHPC recommends that HRSA amend the patient definition to allow 340B hospitals to fill such prescriptions if: (1) the hospital has been involved in the continuum of care related to the condition being treated by the non-hospital prescriber, (2) the services provided by the hospital is reimbursable on the hospital’s cost report, and (3) the prescription is filled within a year of the patient receiving care from the hospital.

Mitchell says that HRSA will consider PHPC’s comments as his office drafts guidance on this matter.

The second issue that OPA plans to address with more detailed guidance is the current prohibition against the use of multiple contract pharmacies by covered entities that do not operate their own outpatient pharmacies.

Currently, these entities are permitted to contract with an outside pharmacy to dispense outpatient drugs to their patients. However, the guidelines currently state that these entities may only contract with one such pharmacy site.

According to Mitchell, the original purpose of this rule was to limit the possibility that these drugs would be diverted to non-patients that also use the contracted pharmacy.

However, Mitchell says that OPA’s recent experience with the Alternative Methods Demonstrations Project program—under which a number of entities have received approval from OPA to operate multiple contract pharmacy arrangements—has provided the agency with evidence that these arrangements can be operated effectively while still protecting against the diversion of 340B drugs to non-patients.

“We have seen no examples of anything other than pristine control of distribution systems,” says Mitchell, adding that his agency is convinced that all pharmacies have the tools to ensure that diversion does not occur.
Some Manufacturers Wary of New Medicare Guidance on PAPs

As both providers and manufacturers prepare for the launch of the Medicare Part D drug benefit on January 1, questions still remain about the future of manufacturer-sponsored patient assistance programs (PAP) and their role in providing financial assistance to low-income and uninsured patients.

As reported in The Monitor last month, the Centers for Medicare and Medicaid Services (CMS) released guidance on July 1 that limits the role that product-donation PAPs—whereby manufacturers offer free drugs to patients rather than cash assistance—can play in assisting Medicare patients to accumulate true out-of-pocket expenses (TrOOP) and begin receiving Medicare Part D “catastrophic coverage.” (see The Monitor, July 2005). CMS’s guidance can be found on the agency’s website at: http://www.cms.hhs.gov/pdps/cob.asp.

The guidance states that manufacturers that donate drugs to Medicare beneficiaries through PAPs may only count towards TrOOP the “actual cost” of manufacturing the drug rather than the cost at which the drug is sold in the retail market.

The notice also encourages manufacturers that currently operate product-donation PAPs to consider offering cash assistance in the form of a “retail ID card” that beneficiaries could present at the point of service to obtain PAP financial assistance through a co-pay assistance program. These programs would allow the beneficiary to count the entire cash value of the manufacturer’s contribution towards TrOOP.

Nonetheless, the new guidance could prove to be problematic for manufacturers and may lead them to abandon product-donation PAPs, according to Bill Shearer, a Managing Partner at Franklin Group, Inc., a consulting firm that provides assistance to manufacturers that administer PAPs.

Shearer and others are particularly concerned about the potential chilling effect on institutional PAPs (IPAP), which involve the donation of drugs to hospitals, clinics, and other health care institutions to replenish drugs dispensed to patients who qualify for the PAP.

According to Shearer, manufacturers may be discouraged from operating such programs in this new regulatory environment because it would require them to disclose their actual costs of production, which they consider to be proprietary information. Furthermore, if manufacturer contributions are limited in the manner that is described in the guidance, Shearer says that manufacturers may conclude that their product donations will not be beneficial to patients because they would still be unlikely to reach the catastrophic coverage limit.

“[Drug manufacturers] want to help with copays,” he says. “Helping Medicare be successful is in the best interest of the manufacturers.”

Though he speculates that some manufacturers may opt to donate cash assistance instead of providing free drug products—as suggested in the CMS guidance—Shearer says that most manufacturers would prefer to continue operating their own PAPs.

This issue was discussed in detail at the 340B Coalition Conference in Washington, DC on July 13. In addressing a session on PAPs, Vicki Robinson, Chief of the Industry Guidance Branch at the US Department of Health and Human Services Office of Inspector General (OIG), said that manufacturers’ efforts to provide financial assistance to patients can potentially present issues related to fraud and abuse laws and the anti-kickback statute.

OIG has existing guidance on Part B premium assistance and has recommended that manufacturers use that model for other kinds of patient assistance. However, Robinson noted that OIG welcomes the opportunity to address other issues related to PAPs, including whether IPAPs should be permitted to provide drugs to institutions in cases where Medicare is not billed.

“We are considering whether additional guidance is needed and viable,” Robinson said, adding that the agency is seeking “practical and workable solutions” to the federal government’s fraud and abuse concerns.
Republican Leaders Call for More Transparency in 340B Pricing

continued from pg. 1

data available to covered entities (PHPC)—an organization that represents approximately 300 DSH hospitals participating in the 340B program—estimates that this provision would save the Medicaid program over $100 million annually.

“This bill would not only provide relief to hospital pharmacies that are struggling to provide pharmaceutical care to our most vulnerable patients, it would also significantly reduce costs to Medicaid at a time when Congress is faced with very difficult budget decisions,” said Ted Slafsky, PHPC’s Executive Director.

Aside from the inpatient extension, the bill—which has been endorsed by the American Hospital Association (AHA)—also proposes that Critical Access Hospitals (CAH) be admitted as “covered entities” under the 340B program. These hospitals are defined as institutions with 25 beds or less that provide emergency care to patients in remote rural areas. Unlike DSH hospitals, which are reimbursed based on Medicare’s prospective payment system, CAHs are reimbursed for the cost of the service they provide and are therefore not currently eligible for 340B pricing.

CAHs are not the only class of providers that has received legislative support recently in their efforts to gain covered entity status under 340B. S. 1563, introduced by Sen. Mike DeWine (R-OH) and Sen. Blanche Lincoln (D-AR) on July 29, calls for the expansion of the 340B program to include children’s hospitals as covered entities.

The bill, entitled “The ABCs of Children’s Health Care Act of 2005,” is a comprehensive piece of legislation that introduces measures to reform the Medicaid program so that it better serves children covered by the program.

According to the bill, these hospitals would have to meet the same standards of ownership status as DSH hospitals and provide a significant amount of indigent care in order to qualify for 340B.

On the same day that S. 1563 was introduced—and just two days before H.R. 3547 was introduced—seven members of the Senate Republican leadership led by Majority Leader Bill Frist (R-TN) introduced the “Healthy America Act of 2005” (S. 4), a health care bill aimed at slowing the growth of health care costs through a variety of measures, including the introduction of significant changes to the 340B program. Specifically, Sec. 332 of the bill would introduce new oversight measures to the program and allow covered entities to partner with multiple contract pharmacies.

One of the most notable 340B provisions in the bill would make ceiling price data available to covered entities through a password-protected website. Currently, covered entities are unable to verify that they are receiving the correct 340B prices for covered outpatient drugs, which has raised questions as to whether entities are being overcharged.

A second measure would require the Secretary of the US Department of Health and Human Services (HHS) to develop a system to verify the accuracy of the data published on the Office of Pharmacy Affairs (OPA) database of covered entities. This proposal is a response to an HHS Office of Inspector General (OIG) report released last year, which found widespread errors in the contact information submitted by 340B entities (see pg. 6).

S. 4 would also require the HHS Secretary to (1) develop a third-party auditing system to ensure compliance by both manufacturers and covered entities, (2) issue more detailed guidance on the 340B definition of “patient,” and (3) establish an advisory opinion system to allow stakeholders to submit questions based on specific factual circumstances and receive guidance from OPA.

In addition, the bill includes a provision that would eliminate the current prohibition against 340B hospitals using group purchasing organizations (GPO) or other group purchasing arrangements for covered outpatient drugs.

Many provisions in the bill, which also promotes the expansion of community health centers (CHC) and rural health centers (RHC), closely resemble a set of proposals developed by the Senate Republican Task Force on Health Care Costs and the Uninsured—which consisted of Republican members of the Senate Committee on Health, Education, Labor, and Pensions—in May 2004.

The Senate bill also includes measures aimed at reforming the medical liability system and expanding access to Health Savings Accounts (HSA).

The bill is expected to receive strong support from the Bush administration. However, some provider groups have already shown strong resistance to a number of the bill’s non-340B-related provisions.
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The failure of states to implement adequate procedures for recording and collecting Medicaid drug rebates paid by pharmaceutical manufacturers has led to decreased state revenues and impeded the ability of the Centers for Medicare and Medicaid Services (CMS) to effectively monitor the program, according to a recent study conducted by the US Department of Health and Human Services Office of Inspector General (OIG).

The July 2005 OIG report, entitled “Multistate Review of Medicaid Drug Rebate Programs” (A-06-03-00048), summarizes the results of an OIG audit of 49 states and the District of Columbia with respect to their rebate reporting and collection practices.

The Medicaid drug rebate program, established in 1990, requires pharmaceutical manufacturers to pay rebates to states in exchange for having their drugs covered by the Medicaid program. To collect the rebates, states are required to bill manufacturers based on a unit rebate amount calculated by CMS and then report their rebate information to the federal government.

Despite notable improvement since the release of a similar report in 1993, OIG’s new report identifies five practices that contribute to inaccurate rebate reporting and accounting: (1) improper information submitted to CMS, (2) improper accounting of interest on late rebates, (3) inadequate rebate collection systems, (4) inadequate dispute resolution processes, and (5) “other significant problems,” including failure to track rebate amounts, inadequate controls over writeoffs and adjustments, and an improper segregation of duties.

“As a result [of these weaknesses], States lacked adequate assurance that all drug rebates due to the States were properly recorded and/or collected,” the report states. “Additionally, CMS did not have reliable information to properly monitor the drug rebate program.”

According to the report, the only states that have implemented safeguards to protect against all of these errors are Illinois, Maryland, Minnesota, and North Carolina. Arizona, the one state not included in the analysis, does not operate a rebate program because nearly all of the state’s Medicaid beneficiaries are enrolled in managed care plans.

The most common weaknesses exhibited by states, according to the report, are their failure to accurately report information to CMS on the CMS 64.9R form, which requires information on rebate billings, collections, adjustments, and uncollected balances.

According to the report, 37 states currently do not provide accurate information on this form, which means that “CMS cannot provide adequate oversight of drug rebate collections.”

The OIG also found that a number of states do not properly track the payments they receive from manufacturers. For instance, 11 states do not have a rebate general ledger control account, which means that they cannot verify that they are collecting all of the rebate revenue to which they are entitled.

Other potential pitfalls identified in this area include the failure to make rate adjustments to the system and the inability to track records throughout the history of the program.

The need for more accurate and timely reporting of Medicaid rebates by states is a major component of the Medicaid recommendations recently put forth by the National Association of Chain Drug Stores (NACDS).

“Prior federal audits have identified $2.1 billion in uncollected drug rebates and $367 million in uncollected pharmacy reimbursements from third parties,” according to the report’s executive summary. The NACDS report, submitted on August 10, also calls for the increased use of generic drugs, enhancement of state preferred drug lists, and Medicaid reimbursement reform.
According to Mitchell, these database errors are exacerbated by the fact that some ineligible entities were incorrectly input into the system at the program’s inception because of the short timeline given to the government to launch the program. Only now is OPA capable of verifying their eligibility.

“In 1992 the program was ramped up in a month,” he says. “We have not had the resources to verify the database since that time.”

As a first step towards re-verifying the eligibility of covered entities, OPA and PSSC have focused on program participants that receive grants from the Centers for Disease Control (CDC)—including tuberculosis (TB) and sexually transmitted disease (STD) clinics—and Title X clinics that receive funding from HRSA’s Office of Population Affairs.

Over the last year, the number of family planning clinics enrolled in the program has decreased slightly from 5,208 in July 2004 to 5,152 in July 2005. OPA projects a further decrease over the next two years, according to Mitchell.

A similar drop-off has occurred in the number of CDC grantees in the program, as 100-120 records have been eliminated by OPA and PSSC over the past year “for various reasons,” according to Mitchell.

With respect to Title X clinics, which are not required under the law to be recertified by OPA, Mitchell says that a number of these providers receive grants strictly for educational purposes, and that the Title X Office—an agency within the Office of Population Affairs—will soon begin a process to determine whether the scope of their grantees’ grants include the provision of family planning drugs.

To do so, the Office of Population Affairs will begin contacting their 85 family planning grantees requesting that they voluntarily re-verify their clinics based on their grant status.

“The Title X office will be helping us to improve the integrity of the grantees on our website,” says Mitchell. “Some of [these entities] are not funded to provide broad-based health care.”

According to Mitchell, an entity is only eligible for the 340B program if it receives grants that include the provision of pharmaceuticals.

It has not been determined as of yet how individual clinics will be formally notified of their removal from the program, though the covered entity database is currently designed to automatically send an e-mail message to entities if they have been removed.

If a provider is removed from the program, Mitchell says that they may appeal the decision by formally contacting OPA to request a review.
The Centers for Medicare and Medicaid Services (CMS) have released new estimates regarding the size of the premium subsidies that low-income Medicare beneficiaries will receive once enrolled in the new Medicare prescription drug benefit.

Under the new drug benefit, which will go into effect on January 1, subsidies will be made available to those beneficiaries who meet certain income and asset requirements. (For a detailed explanation of the various income levels, see *The Monitor*, December 2004). These subsidies are designed to assist beneficiaries with paying down the premiums, copays, and deductibles required by their prescription drug plan (PDP) or Medicare Advantage (MA) plan.

According to a CMS memo released on August 9, the size of the subsidies in each state will be largely dependent on the average premium amount charged by drug plans in each region and may not necessarily cover a beneficiary’s entire premium amount.

More specifically, the memo states that the premium subsidy will be equal to the lesser of either (1) the beneficiary’s premium amount or (2) an adjusted figure derived from the premiums charged by the plans in his/her region.

The size of the estimated subsidies ranges widely from region to region. The lowest subsidy amount appears in California ($23.25) and the highest will be available in Mississippi ($36.39). Estimates for all regions are located at: www.cms.hhs.gov/healthplans/rates.

“Based on these benchmarks, CMS expects that people who qualify for this extra help will have multiple prescription drug plan choices with no premiums.”

CMS Release

CMS continues to assert that “most beneficiaries with limited incomes will also have no deductibles, no gaps in coverage, and only small copayments for each prescription.”

The CMS memo also presents data on the estimated monthly premium amounts for each region. According to the memo, the average size of the monthly premium for all PDP and MA plans will be $32.20.

This estimate, based on the data received by CMS from potential PDP and MA plans, is approximately $5 less than the figure included in the Medicare Trustees’ report, which was released in March.

CMS contends that this decrease is due to the fact that the value of the actual bids submitted by PDP and MA plans has been lower than expected due to strong competition. As a result, CMS has stated that plans will now have to lower their costs in order to attract beneficiaries.

“Plans that do not offer low costs for high-quality benefits will have to charge higher premiums and will not attract beneficiaries,” according to CMS. The agency suggests that plans can reduce their costs by negotiating lower drug prices and encouraging the use of generic drugs and other less costly medication alternatives.

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